



6-4-07

yfw

CASE BP/G-32575A

EV 786957237  
Express Mail Label Number

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

5 | 31 | 2007  
Date of Deposit

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF

BETZ ET AL.

INTERNATIONAL APPLICATION NO: PCT/EP03/07349

FILED: 8 JULY 2003

U.S. APPLICATION NO: 10/520,568 ✓

35 USC §371 DATE:

FOR: LIQUID FORMULATIONS WITH HIGH CONCENTRATION OF  
HUMAN GROWTH HORMONE (HGH) COMPRISING 1,2-  
PROPYLENE GLYCOL

## MS: Amendment

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

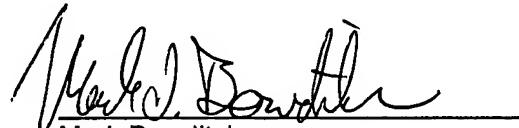
This paper is supplemental to the Information Disclosure Statement filed January 7, 2005. Since Applicants believe this paper is being filed before the mailing date of a first Office Action on the merits, no fees are believed to be required under 37 C.F.R. §1.97(b)(3). If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

Copies of these references are enclosed herewith.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,



Mark Bowditch  
Attorney for Applicants  
Reg. No. 40,315

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080  
(609) 627-8507

Date: 5/31/2007

**INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)



ATTY. DOCKET NO.  
BP/G-32575A  
APPLICATION NO.  
10/520,568  
APPLICANT  
BETZ ET AL.  
FILING DATE

Group

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA	5,597,802	1/28/97	Clark et, al.			
	AB	4,857,505	8/15/89	Volker D. Arendt			
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						
	AL						

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION YES	NO
	AM	EP 0 303 746	2/22/89	International Minerals			<input type="checkbox"/>	<input type="checkbox"/>
	AN	EP 0 211 601	7/29/86	International Minerals			<input type="checkbox"/>	<input type="checkbox"/>
	AO	AU A-60733/86	2/5/87	International Minerals Corp			<input type="checkbox"/>	<input type="checkbox"/>
	AP	WO 1991/14454	4/2/91	Skua Investments Ltd			<input type="checkbox"/>	<input type="checkbox"/>
	AQ	AU A-611856	9/5/90	Chungai Seiyaku			<input type="checkbox"/>	<input type="checkbox"/>

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)**

	AR	Physicians Desk Reference, PDR 43, 1989 Edition 989-990
	AS	Peter Goddard, " Therapeutic proteins- a Pharmaceutical perspective", 1990, pgs103-131
	AT	Isosmotic and Isotonic Solutions, pgs 521-526

EXAMINER	DATE CONSIDERED
----------	-----------------

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

(Use several sheets if necessary)

ATTY. DOCKET NO.  
BP/G-32575A  
APPLICATION NO.  
10/520,568  
APPLICANT  
BETZ ET AL.  
FILING DATE

Group

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
BA						
BB						
BC						
BD						
BE						
BF						
BG						
BH						
BI						
BJ						
BK						
BL						

## FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION YES	NO
BM	WO 1989/02751	9/26/88	Cetus Corporation			<input type="checkbox"/>	<input type="checkbox"/>
BN	WO 1991/11200	8/8/91	Janssen Pharma			<input type="checkbox"/>	<input type="checkbox"/>
BO	WO 1995/28174	3/30/95	Genentech, Inc			<input type="checkbox"/>	<input type="checkbox"/>
BP						<input type="checkbox"/>	<input type="checkbox"/>
BQ						<input type="checkbox"/>	<input type="checkbox"/>

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

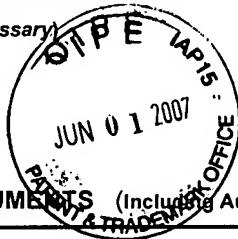
BR	Thurow " Stabilisation of dissolved proteins against denaturation at hydrophobic interfaces", 1984, Diabetologica, pgs 212-218
BS	Attar S. Chawla" Aggregation of Insulin, containing surfactants, in contact with different materials", pgs 420-424
BT	Physicians Desk Reference, PDR 39, Edition 1985, pgs 1940-1941

EXAMINER \_\_\_\_\_ DATE CONSIDERED \_\_\_\_\_

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

## INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

ATTY. DOCKET NO.  
BP/G-32575A  
APPLICATION NO.  
10/520,568  
APPLICANT  
BETZ ET AL.  
FILING DATE

Group

EXAMINER  
INITIAL

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	DA	Journal of Parenteral Science and Technology , Technical Report 10 " Parenteral Formulations of Proteins and Peptides: Stability and Stabilizers", 1988, pgs 2-26
	DB	
	DC	
	DD	
	DE	
	DF	
	DG	
	DH	
	DI	
	DJ	
	DK	
	DL	
	DM	
	DN	

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.